

XIAFLEX®

for PEYRONIE'S DISEASE

(Zi-a-flex)

Collagenase clostridium histolyticum – 900 micrograms powder and diluent for solution for injection.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about XIAFLEX.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having XIAFLEX against the benefits they expect it will have.

If you have any concerns about this injection, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What XIAFLEX is used for

XIAFLEX is used to treat adult men with Peyronie's disease who have a 'plaque' that can be felt and a curve to their penis.

Peyronie's disease can cause a change in the shape of the erect penis due to the abnormal buildup of scar tissue, known as a plaque, within the stretchy fibres of the penis.

The plaque may interfere with the ability to get a straight erection because the plaque will not stretch as much as the rest of the penis.

Men with Peyronie's disease may have an erection that is curved or bent.

Peyronie's disease does not occur in females.

How it works

The active substance is collagenase clostridium histolyticum, and is naturally produced by a bacterium named Clostridium histolyticum.

Peyronie's Disease

XIAFLEX is injected by your doctor into the plaque in your penis which may help break down the plaque that is causing your erect penis to curve.

This may help the erection to be straighter and may enable you to feel less bothered by your Peyronie's disease.

Before you are given XIAFLEX

Do not use XIAFLEX if:

1. You have an allergy to collagenase clostridium histolyticum or any of the ingredients listed at the end of this leaflet

Please consult a doctor immediately if you experience any signs or symptoms of a serious allergic reaction:

- wide spread redness or rash
- swelling
- tightness in the throat or difficulty breathing
- chest pain.

2. You have taken anticoagulation medicine within the last 7 days.

One exception is the use of up to 150mg daily dose of acetylsalicylic acid (also called aspirin, a substance present in many medicines used to prevent blood clotting) which can be taken.

3. Your Peyronie's plaque is located close to structures (like the urine tube) which may be damaged as a result of the injection.

Do not use XIAFLEX in children under 18 years of age.

There is not enough information at present to recommend use of XIAFLEX in children.

Do not use XIAFLEX after the expiry date printed on the pack.

Do not use XIAFLEX if the packaging is torn or shows signs of tampering.

If you are not sure whether you should have XIAFLEX, talk to your doctor or pharmacist.

Before you are given this medicine

Tell your doctor:

- if you have any allergies to any other medicines, any other substances, such as foods, preservatives or dyes
- if you have had an allergic reaction to a previous XIAFLEX injection
- if you are thinking about receiving or have previously received XIAFLEX to treat Peyronie's Disease.
- if you have a history of problems with the normal clotting of your blood or if you are taking any medicines to help control the normal clotting of your blood (known as anticoagulation medicines).
- if you are taking or have recently taken anthracyclines/anthraquinone derivatives such as doxorubicin and some tetracycline antibiotics such as doxycycline used to treat infections.
- if you think your curvature is greater than 90° and / or you have had Peyronie's disease for less than 1 year.

If you have not told your doctor about any of the above, tell them before you start using XIAFLEX.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and XIAFLEX may interfere with each other.

Tell your doctor or pharmacist if you are using any medicine to thin your blood such as warfarin, clopidogrel or dabigatran. Some people refer to anticoagulation medicine as "blood thinners". If you are not sure, please check with your doctor or pharmacist.

XIAFLEX must not be given within 7 days of the last dose of your anticoagulation medicine. One exception is the use of up to 150mg daily dose of acetylsalicylic acid (also called aspirin, a substance present in many medicines used to prevent blood clotting) which can be taken.

Tell your doctor or pharmacist if you are taking or have recently taken anthracyclines/anthraquinone derivatives such as doxorubicin, and some tetracycline antibiotics such as doxycycline used to treat infections. XIAFLEX should not be given

within 14 days of receiving tetracycline antibiotics.

These medicines may be affected by XIAFLEX, or may affect how well it works. (You may need different amounts of these medicines, or you may need to take different medicines.) Your doctor or pharmacist will advise you and decide whether or not to give the Injection.

How XIAFLEX is given

Your doctor will perform all injections of XIAFLEX.

XIAFLEX should only be used by an approved practitioner who will be able to display (or show you) such an authorisation.

This medicine must only be injected into the plaque of your penis by your doctor.

XIAFLEX is given as part of a treatment cycle. In each treatment cycle, you will receive one injection of XIAFLEX, followed by a second injection on a separate day (1 to 3 days later).

How much is given

The recommended dose of your prescribed medicine is 0.58 mg.

Your doctor will inject XIAFLEX into the plaque that is causing your penis to curve.

Clinical study experience with XIAFLEX is currently limited to four treatment cycles in which a total of 8 injections may be administered into the plaque causing the curvature.

If you take too much (overdose)

As this product is administered to you by your doctor it is very unlikely that you will be given an incorrect dosage. In the unlikely event that your doctor administers a higher dosage than recommended, you may experience an increase in the severity of possible side effects especially reactions at the injection site listed under "Side Effects" in this Leaflet.

You can telephone your doctor or the Poisons Information Centre for advice on overdose management.

Poison Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

If you have any further questions on the use of this product, ask your doctor or pharmacist.

After having XIAFLEX

Things you must do

Be sure to ask your doctor when you can resume normal activities after treatment with XIAFLEX. Your doctor should tell you when you can resume sexual activity after each treatment cycle. Your doctor will also tell you when to come back if more treatment cycles are needed.

After each injection of XIAFLEX, your penis may be wrapped with a bandage. Your doctor will tell you when to remove the dressing.

One to three days after the second injection of XIAFLEX in a treatment cycle, you will need to return to your doctor for a manual procedure that will help stretch and help straighten your penis. Your doctor will tell you when to come back for this.

Your doctor will show you how to gently stretch and straighten your penis the right way. See “How to gently stretch your penis” and “How to gently straighten your penis”. You should continue the stretching and straightening yourself at home for 6 weeks after each treatment cycle.

How to gently stretch your penis

Gently stretch your penis 3 times a day for approximately 6 weeks. Only stretch your penis if your penis is not hard (erect).

- With one hand, hold the tip of your penis with your fingers. With the other hand, hold the base of your penis with the fingers.
- Gently pull your penis away from your body to its full length and hold the stretch for 30 seconds.
- Let go of the tip of your penis and let your penis return to its normal length.

How to gently straighten your penis

Gently straighten your penis once a day for approximately 6 weeks. Only straighten your penis if you have an erection that happens without any sexual activity (spontaneous erection). Bending your penis should not cause any pain or discomfort.

- With 1 hand hold your penis. With your other hand, gently bend your penis in the opposite direction of the curve.
- Hold the penis in this more straightened position for 30 seconds, then let go.

Keep follow-up appointments with your doctor.

Tell your doctor immediately if:

- you have any of the symptoms of infection such as fever, chills, increased redness or swelling
- you have trouble stretching or straightening your penis, or if you have pain or other concerns.

Things to be careful of

Do not have sex or have any other sexual activity for at least 2 weeks after the second injection of a treatment cycle with XIAFLEX and after any pain and swelling has gone away.

After treatment with XIAFLEX, blood vessels in your penis may also break, causing blood to collect under the skin (which is called a haematoma). This could require a procedure to drain the blood from under the skin.

Receiving an injection of XIAFLEX may cause damage to the tubes in your penis called the corpora. After treatment with XIAFLEX, one of these tubes may break during an erection. This is called a corporal rupture or penile fracture. This could require surgery to fix the damaged area.

Damage to your penis might not get better after a corporal rupture.

Symptoms of penile fracture (corporal rupture) or other serious injury to your penis may include:

- a popping sound or sensation in an erect penis

- sudden loss of the ability to maintain an erection
- severe pain or swelling in your penis
- purple bruising and swelling of your penis
- difficulty urinating or blood in the urine.

Call your doctor right away if you experience any of the symptoms of penile fracture or serious injury to your penis listed above.

If you continue to have problems with erections or sex after the XIAFLEX injections, talk to your doctor about other causes and/or treatments for these problems.

You must avoid potentially hazardous tasks such as driving or operating machinery until you know how XIAFLEX affects you or as advised by your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having XIAFLEX.

Like all medicines, XIAFLEX can cause side effects, although not everybody gets them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

These are the more common side effects of XIAFLEX. Mostly these are mild and short-lived.

Most of the side effects that occurred in the clinical studies were mild or moderate in severity and most resolved within 2 weeks of the injection.

Very common side effects:

- bruising or swelling of the penis and pain in the penis. This pain should be relieved by over-the-counter pain relief medicines.
- a small collection of blood under the skin at the injection site.

Common side effects:

- reactions at the injection site such as presence of a blister, swelling, itching or a solid raised area under the skin
- pain at the injection site and above the penis
- blister or redness/dischloration of the penis
- genital itchiness
- painful erection
- painful sex
- erectile dysfunction
- blood blister.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Contact your doctor immediately if you experience any of the symptoms of penile fracture or other serious injury to your penis. These include:

- a popping sound or sensation in an erect penis
- sudden loss of the ability to maintain an erection
- severe pain or swelling in your penis
- purple bruising and swelling of your penis

- difficulty urinating or blood in the urine.

See “Things to be careful of”

You may experience serious side effects which need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

Sudden signs of allergy such as:

- widespread redness or rash
- swelling
- tightness in the throat or difficulty breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

As with any non-human protein medical product, the potential long term risk of autoimmune disease cannot be excluded.

All of these side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Storing XIAFLEX

XIAFLEX is usually stored in the doctor’s surgery or clinic, or at the pharmacy.

However, if you need to store XIAFLEX at home:

- **Keep out of the reach and sight of children.**
- **Keep XIAFLEX in the original pack until it is time for it to be given.**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze XIAFLEX.**

After reconstitution, the medicine can be used immediately. Alternatively, reconstituted XIAFLEX can be kept at ambient room temperature (20°C-25°C) for up to one hour or refrigerated at 2°C-8°C for up to 4 hours prior to administration. If refrigerated, the reconstituted solution must be allowed to return to ambient room temperature (20°C-25°C) for approximately 15 minutes before use.

Your doctor must not use XIAFLEX if the reconstituted solution is discoloured or contains particles.

The reconstituted solution must be clear, colourless with no lumps or flakes or particles.

Your doctor will take care of storing, handling and disposing of XIAFLEX.

Medicines must not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Product description

What it looks like

XIAFLEX is supplied as a white powder in a 3 mL clear glass vial with rubber stopper, aluminium seal and flip-off plastic cap.

The 3 mL diluent that is used to dissolve the powder is supplied as a clear liquid in a 5 mL clear glass vial with rubber stopper, aluminium seal and flip-off plastic cap.

XIAFLEX is supplied in a single use pack containing 1 vial of XIAFLEX powder and 1 vial of diluent.

Ingredients

Each vial of XIAFLEX 900 micrograms powder contains:

Active ingredients:

collagenase clostridium histolyticum

Inactive ingredients:

sucrose, trometamol, hydrochloric acid.

Each vial of diluent contains:

Ingredients

calcium chloride, sodium chloride, water for injection.

Sponsor

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